EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
v.	)	Count One: Receipt of Misbranded Drugs in Interstate Commerce (21 U.S.C. §§ 331(c), 333(a)(1))
GREATER BOSTON BEHAVIORAL HEALTH LLC,	)	
Defendant.	)	Forfeiture Allegation: (18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

AGREED-TO STATEMENT OF FACTS

Greater Boston Behavioral Health LLC ("GBBH") agrees to the accuracy of the following statement of facts:

The Defendant

1. GBBH was a Massachusetts corporation providing medical services to patients, including treatment for chronic pain and migraines.

Botox® and Botox® Cosmetic

2. Botox® and Botox® Cosmetic were brand names of drugs manufactured by Allergan, Inc.,[1] which, respectively, have been approved by the United States Food and Drug Administration ("FDA") for the treatment of crossed eyes and spasm of the eyelids, and for the temporary improvement in the appearance of glabellar lines, commonly referred to as wrinkles. FDA's approvals for Botox® and Botox® Cosmetic limited them to use under the supervision of a licensed practitioner and required that their labels bear the symbol "Rx only."

3. In 2009, FDA approved several revisions to the labeling for Botox and Botox Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black

[1] Allergan was acquired by AbbVie, Inc. in a transaction completed in May 2020.

box warning") cautioning that the effects of Botox and Botox Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that the different botulinum toxin products are not interchangeable because the units used to measure the products are different.

GBBH's Purchase and Use of Foreign Unapproved Botox

4. Beginning in 2012, GBBH sought out sources from which it could purchase Botox® that was manufactured, packaged, and labeled for sale in the United Kingdom and other foreign countries ("foreign Botox"). From 2012 through June 2019, GBBH purchased foreign Botox from a number of different sources.

5. The label of the foreign Botox purchased by GBBH differed from the FDA-approved label for Botox® and Botox® Cosmetic and lacked the designation "Rx Only" as required by the FDCA for prescription drugs. The label also typically did not include the FDA-required "black-box warning" concerning potential side-effects of Botox.

6. GBBH purchased foreign Botox at prices significantly below the price that Allergan and its authorized distributors charged for Botox® and Botox® Cosmetic that was manufactured and labeled for sale in the United States.

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7. Doctors at GBBH used the foreign Botox to treat patients suffering from migraine headaches and did not disclose to these patients that they purchased the drug from foreign sources or that it was not labeled for distribution in the United States.

Greater Boston Behavioral Health LLC
Defendant
By: Elliot M. Weinstein
Authorized Representative

Date: 4/13/23

Paul Shaw
Attorney for Defendant

Date: 4/13/2023